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09/990,080	11/21/2001	Gregg B. Morin	018/258C	2136

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EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,080	MORIN, GREGG B.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-21* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Amendment and Response to Office Action under 37 CFR § 1.111 filed on Oct. 8, 2004 is acknowledged. The amendments to the specification, abstract and claims have been entered. Claim 8 is canceled; claims 1-7, 9, 11, 13-14 and 16-17 are amended; claim 21 is added. Claims 1-7 and 9-21 are pending. After the amendment, claims 1-7, 10, 12 and 16-17 in their entirety and claims 9, 11, 13 to 15 and 21 in part, are the subject of this Office Action. Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

1. Election/Restriction

In response to the restriction request of Jan. 14, 2004, wherein the restriction to one of the following invention was required under 35 U. S. C. 121:

group I. claims 1, 2, 5, 6, 7 (all in part), claims 8 and 9, claims 13, 14 and 15 (all in part), claims 18, 19 and 20, claim 10-12 (both in part) drawn to protein, peptide or peptide mimetic comprising at least 10 consecutive amino acid in SEQ ID NO: 2, in particular at least 10 consecutive amino acids in SEQ ID NO: 4, and a sequence comprising SEQ ID NO: 3 and 5, and to the method of use for inhibiting telomerase catalytic activity; classified in class 424 subclass 94.5;

group II. claims 1, 2 (both in part), 3, 4, claims 5, 6, 7, 13, 14, 15 (all in part), 16, and 17, claims 1-12 (both in part) drawn to polypeptide that comprises at least 10 consecutive amino acid from the polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1 wherein the encoded peptide contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-66, 748-766, 1055-1071, 1084-116 of SEQ ID NO:2, and to the method of use for inhibiting telomerase catalytic activity; classified in class 424 subclass 94.5;

Applicants elected in their Response of Feb. 20, 2004, without traverse, the invention of Group II. Group II consisted of claims 1, 2, 5, 6, 7, 10, 11, 12, and 13-15 all in part, and claims 3, 4, 16 and 17 in their entirety, and was drawn to protein, or peptide or peptide mimetics that comprises at least 10 consecutive amino acid from the polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1 wherein the encoded peptide contained one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-66, 748-766, 1055-1071, 1084-116 of SEQ ID NO:2, as well as to a method of use said proteins, polypeptides, polypeptide mimetics for inhibiting human telomerase reverse transcriptase.

In result of the amendment, claims 1-7, 10, 12 and 16-17 in their entirety and claims 9, 11, 13-15 and 21 in part are currently encompassed by Group II.

Applicant requests the subject matter of claims 18-20 withdrawn from examination be rejoined into the group under examination upon determination that the group under examination is free of prior art. Their reason for this request is claims 18-20 depend on claim 15 i.e., on independent claim 13 and that dependent claims 9, 11 14, 15, and 21 serve the function of linking the species in the elected group and the withdrawn group.

Applicant's request has been considered. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Objections

2.1. Specification

Objection to the specification made in the previous Office Action is, because the amendments have been entered.

Table 1 is objected to for lack of columns describing mutants' ability to bind RNA and human telomeres.

Table 1 is objected to for lack of data indicating which of the mutants is a negative dominant mutant, i.e., according to the definition given on page 14 of the Applicant's Remarks, of Oct. 8, 2004, "effectively inhibit[s] the native form of the molecule by at least 50% when both are present in equimolar quantities."

There is an unnecessary insert &&& in line 40 of page 3.

2.2. Claims

Please correct the claims to recite telomerase reverse transcriptase.

Currently amended claims are directed to chemical structures that contain about and more than 500 amino acids. Formally, only structures containing up to 100 amino acids are called peptides. Applicant, therefore, claims polypeptides.

3. Rejections

3. 1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Rejection of claim 1 and 16, as being indefinite for the reasons indicated in the first Office action on merits, dated April 20, 2004 (previous Office action) is withdrawn, because the claims have been amended.

Rejection of claims 5-7, 13-17 for the use of limitation "dominant negative mutant" is withdrawn, because Applicant's arguments are found persuasive and the claims have been amended.

Claims 1-3, 5-7, 16 and 17 were previously rejected for the use of the limitation "deletions consisting essentially of". The amended claim 1-3, 5-7, 16 and 17 are still rejected because parts a) and b) of claim 1 and 2 are indefinite. It is unknown which additional amino acids are included and excluded from the scope of parts a) and b). The phrase "deletions consisting essentially of" is for the purpose of searching and applying prior art construed as equivalent to "comprising"; see MPEP 2111. 03 "Transitional Phrases".

Traversing the above rejection of claims 1-3, 5-7, 16 and 17 Applicants write in their Remarks of Oct. 8, 2004,

"Applicant respectfully disagrees. The skilled reader will appreciate the term to mean that the user will make the deletions to the same regions of the TRT protein indicated in the claim, but has the option of making minor adjustments in the exact length of the deletion so long as if has the same effect of inactivating the reverse transcriptase activity of the protein. Applicants seek this coverage so as to adequately protect the invention. Now that the inventors have shown where the functionally sensitive regions are located within the 1132 amino acids of the TRT molecule the skilled reader may readily tinker with deletions in the same regions without undue experimentation, expecting the same results" page 14, the fifth paragraph.

Applicant's arguments have been fully considered but are found not persuasive for the following reasons. The above rejection is made under 35 USC section 112, second paragraph, and not under 35 USC section 112 first paragraph, for scope of enablement; thus, Applicant's arguments are not pertinent to the rejection.

The rejection of claim 11, 13-17 for the use of the phrases "means that inhibits", "means for inhibiting", "means for binding" and "inhibition means" that are not defined in the disclosure is withdrawn, because Applicant requests the claims were examined in the terms of means and function explicitly provided for in 35 USC §112 paragraph 6; page 16 the section "Means plus function claims". The issue will be addressed below.

3.2. 35 USC, section 112, first paragraph

3.2.1. Lack of written description

Rejection withdrawal

Claims 13-15 were rejected for lack of written description of a dominant negative mutant toward which the claims were directed. This rejection is withdrawn, because the claims have been amended.

Rejection caused by amendment

Claims 1-7 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

After the amendment of Oct. 8, 2004, the claims are directed to a protein, peptide or peptide mimetic, and methods of their use wherein said protein, peptide or peptide mimetic consists of at least 500 consecutive amino acids of SEQ ID NO:2 or at least 500 consecutive amino acids of an amino acid sequence encoded by DNA hybridizing to SEQ ID NO:1, wherein the both at least 500 amino acid sequences contain deletions as defined by the claims. The claims as originally filed and examined in the previous Office action were directed to a protein, peptide or peptide mimetic comprising at least 10 consecutive amino acid in SEQ ID NO:2, or at least 10 consecutive amino acids from the polypeptide encoded by a polynucleotide that hybridizes to SEQ ID NO:1. Thus, the amended claims are rejected because they contain the new matter.

Claims 13, and dependent claims 9, 11, 14, 15, 17 and 21 will be further examined, per Applicant's request, in terms of 35 USC, section 112, six paragraph; see below.

Claims 1, 3, 10 and 2, 4-7 and 12 are rejected as being generic and lacking a sufficient written description for the scope of the claimed. The claims are directed to the following large and variable genera of polypeptides, and methods of their use:

claim 1 a polypetide that inhibits human telomerase and comprises at least 500 consecutive amino acids from a sequence encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1; but which contains one or more deletions, each of which consists essentially of, i.e. comprising:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

claim 2 a polypetide that inhibits human telomerase and comprises at least 500 consecutive amino acids of SEQ ID NO:2, but which contains one or more deletions, each of which consists essentially of, i.e. comprising:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

claim 3 A polypeptide of claim 1, which contains one or more deletions consisting essentially of, i.e., comprising residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO:2 (claim 3); (*For me claim 3 has anyway a bigger scope than claim 1.)*

claim 5 A polypeptide that has(comprises) an amino acid sequence consisting of at least 500 consecutive amino acids of SEQ ID NO: 2; except that it contains one or more deletions consisting essentially, i.e., comprising residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116. of SEQ ID NO: 2, wherein said polypeptide is a dominant negative mutant.

claim 6 a polypetide that has (i.e., comprises) an amino acid sequence consisting of at least 500 consecutive amino acids of SEQ ID NO: 2; except that it contains one or more deletions, each of which consists essentially of:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein such polypeptide binds human telomerase RNA component but lacks processive telomerase activity .

claim 7 a polypetide that has (i.e., comprises) an amino acid sequence consisting of at least 500 consecutive amino acids of SEQ ID NO: 2; except that it contains one or more deletions, each of which consists essentially of:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein such polypeptide binds human telomeres but lacks processive telomerase activity .

Claims 1-7 are lacking written description of structure of deletions consisting essentially of residues 560-565 or 930-934 and deletions consisting essentially of residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2. The disclosure provides representative species that are polypeptides identified by SEQ ID NO: 2, wherein amino acids residues 560-565, 930-934, 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2 are deleted. Providing these species is insufficient for identifying the structure of the all species of the genus, because Applicant does not define the meaning of the term "consisting essentially of". It is unknown, therefore, which additional amino acids are included and excluded from the length scope of deletions that are to be present in the claimed polypeptides. On page 4, line 36 (of substitute specification) one reads "Thus in some embodiments the mutation is a deletion of at least one, typically at least 10 and often at least 25, at least about 50, or at least 100 amino acid residues relative to a naturally occurring hTRT." On the other hand, on page 2 in Summary, one reads "In one embodiment, the hTRT polypeptide has a deletion of at least 25 residues." These description are not consistent and are not a definition of "consisting essentially of". For that reason the transitional phrase "consisting essentially of" is understood as "comprising"; see

MPEP 2111.03. "Transitional Phrases". See also the above rejection under 35 USC section 112, second paragraph. Because of lack of structural characteristics of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 10 and 12 are included in this rejection as being dependent on rejected base claims 1, 2 and 16, because they do not correct the language the claims from which they depend.

Traversing this rejection in the Response of Oct. 8, 2004, Applicant states, "The skilled reader will appreciate the term to mean that the user will make the deletions to the same regions of the TRT protein indicated in the claim, but has the option of making minor adjustments in the exact length of the deletion", page 14, line 17.

Applicant's argument is persuasive in respect to limitations "at least 10 consecutive amino acids from residues 323-450, etc.", included in step c)-g) of claims 1and 2. The limitation as written in the claims refers to deletion consisting essentially of at least 10 amino acids within a fragment of SEQ ID NO:2 having definite limits and length greater than 10 amino acids. Other deletions in claims 1, 2, 3 and their dependents are lacking written description for the reasons indicated above.

Claim 5 is rejected for lack of written description, because the specification does not teach which of the representative polypeptides of the genus of the polypeptides consisting of at least 500 consecutive amino acids of SEQ ID NO: 2; except that it contains one or more deletions consisting essentially, i.e., comprising residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2 are actually dominant negative mutants. Such mutants, according to the definition given on page 14 of the Applicant's Remarks, of Oct. 8, 2004, "effectively inhibit the native form of the molecule [rather SEQ ID:2, because there are native variants human telomerase reverse transcriptase that are themselves inactive] by at least 50% when both are present in equimolar quantities." Table 1 does not show that mutants of SEQ ID NO:2 having themselves less than 1% activity fulfill the requirement of the definition. This is a complete lack of written description of function. Because of lack of disclosure which of the

mutants made by applicants have *in vitro* characteristic of dominant negative mutants, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

3.2.2. Scope of enablement

Rejection of claims 1, 2, 3, 5, 6, 7, 10, 12 in the previous Office action is withdrawn because was improper.

Rejection of claims 13, 11 and 14-17 is not withdrawn.

Claim 13, dependent claims 14 –17, directed to the protein peptide or peptide mimetic that inhibit any telomerase and claims 11 and 21 directed to the method of their use for inhibition of any telomerase are rejected, because the specification why being enabling for inhibiting human telomerase reverse transcriptase of SEQ ID NO:2 by polypeptides disclosed by applicants (see Table 1 of the specification) does not reasonably provide enablement for any protein, peptide or peptide mimetic that inhibits any telomerase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the large number of any protein, peptide and peptide inhibitors of any telomerase (i.e. telomerase reverse transcriptase) that are already known or will be developed. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any inhibitor that is a protein, peptide or peptide mimetics wherein said inhibitor inhibits telomerase form any natural or man-made source.

While methods of gene cloning, gene structure manipulating and testing inhibitory effect of encoded protein on a telomerase are well known in the relevant art, and skills of the artisans highly developed, one skilled in the art is not able to make any peptide or peptide mimetics that inhibits any telomerase reverse transcriptase, because the lack sufficient structural characteristics of inhibitors and telomerase itself makes the probability of success in obtaining the claimed invention rather low. Thus, to make and use the claimed invention one skilled in the art is forced to do research outside the realm of routine experimentation. If a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality intended by Applicants i.e. to inhibition of any telomerase. The provision of inhibitors (Table 1) taught by the specification and human telomerase of SEQ ID NO:2 fails to provide such guidance of the structure of any polypeptide and any telomerase which remain encompassed within the scope of the rejected claims.

Examiner concludes that without the further guidance on the part of Applicants in regards to structure of the claimed inhibitors and origin and structure of telomerase to be inhibited, experimentation left to those in the art is improperly extensive and undue.

4. 35 USC section 112, paragraph 6

Claims 13, and dependent claims 9, 11, 14, 15, 17 and 21 use the terms means and function. In his Remarks of October 8, 2004 Applicant states that claiming an invention in terms of means and function is explicitly provided for in 35 USC § 112, sixth paragraph:

> "An element in a claim for a combination may be expressed as a means or step for perform in a specific function without the recital of structure, materal, or acts in support thereof, and such claim shall be

construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof", page 16 line 22.

Applicant continues,

"the proper test for meeting the definiteness requirements is that the corresponding structure of a means plus function limitation need only be disclosed in the specification in a way that one skilled in the art will understand what structure will perform the recited function."

On page 17, second pargraph Applicant argues,

"*a means for inhibiting telomerase activity* as referenced in the claims are exemplified sufficiently in the specification and in the dependent claims so that the skilled reader will understand what structure is meant. Accordingly, the claims meet the requirements of § 112 paragraph 6 of § 112 paragraph. Withdrawal of these rejections [of claims 13 and dependent claims] is respectfully requested."

This argument of Applicant's has been carefully analysed, but is found not persuasive because one skilled in the art can easily recognize that the scope of the claims covering any inhibitor that is protein, peptide or peptide mimetic and that has means for inhibiting any telomerase is lacking support in the disclosure. The disputed claims are directed to the following subject matter.

Claim 13 is directed to a protein, peptide, or peptide mimetic that has means for inhibiting telomerase activity. The language of the claim is broad; the scope of the claim covers any inhibitor that is a protein, peptide of peptide mimetic and inhibits any activity of telomerase from any organism as well as man-made.

Claim 9 is directed to a peptide mimetic according to claim 13 wherein one or more linkages between consecutive amino acids are chemical groups quoted in the claim.

Claim14 is directed to a protein, peptide, or peptide mimetic of claim 13, which has a means for binding telomerase RNA component, but lacks telomerase activity.

Claim 15 is directed to a protein, peptide, or peptide mimetic of claim 13, which lacks means for binding telomerase RNA component.

Claim 16 is directed to an inhibitor of any activity of any telomerase wherein the telomerase inhibition means are as in claim 1; for details see rejection for lack of written description above.

Claim 17 is directed to and inhibitor of any activity of any telomerase wherein the telomerase inhibition means are as in claims 2; for details see the above rejection for lack of written description.

Although the proper test for meeting the definiteness requirements is that the corresponding structure of a means plus function limitation need only be disclosed in the specification in a way that one skilled in the art will understand what structure will perform the recited function (MPEP page 2100-224 of May 2, 2004 revision, left column, second paragraph), the broad scope of claim 13 and dependent claims does not correspond with the structures disclosed in the specification. The specification discloses 18 polypeptides that are modifications of human telomerase reverse transcriptase sequence of SEQ ID NO:2 (Table1). The inhibitors are obtained by deletion of ;

a) residues 560-565,

b) residues 930-934,

c) residues 323-450.

d) residues 637-660,

e) residues 748-766,

f) residues 1055-1071, or

g residues 1084-1116;

some additional polypeptides that can be derived from SEQ ID NO:2 by deleting

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116.

These polypeptides do not exhibit reverse transcriptase processive activity, and one skilled in the art recognizes they can be used as inhibitors of human telomerase reverse transcriptase of SEQ ID NO:2.

As to the whole scope of the claims **"the invocation of 35 U.S.C. 112, sixth paragraph does not exempt an applicant from compliance with 35 U.S.C. 112, first and second paragraphs. See *Donaldson*, 16 F.3d at 1195, 29 USPQ2d at 1850"**, MPEP page 2100-224 of May 2, 2004 revision, right column, second paragraph, line 19). Applicant does not comply with written description requirements and definiteness requirements because:

1. applicant does not teach reverse transcritpase of any other telomerase, but that which is of human human origin and set forth in SEQ ID NO:2;
2. applicant fails to provide evidence that the disclosed proteins inhibit reverse transcritpase of any other telomerase, originating from other species, or being an active splice variant of human telomerase;
3. the disclosure fails to teach any particular peptide, i.e., a polypeptide that is about or less than 100 amino acids long, having the inhibitory property against any telomerase including SEQ ID NO:2;
4. at least for the reason indicated in point 3 Applicants fail to disclose any peptide mimetics that has means for inhibiting any telomerase;
5. applicants do not disclose a protein, peptide, or peptide mimetic of claim 13, which has a means for binding RNA component for any telomerase from any species or man made, but lacks telomerase activity;
6. applicants do not disclose a a protein, peptide, or peptide mimetic which lacks means for binding RNA component form any telomerase but human of SEQ ID NO:2;
7. applicants do not define what is the meaning of the term "deletions consisting essentially of", i.e. which deletions comprising

    a) residues 560-565,

    b) residues 930-934,

    c) residues 323-450.

d) residues 637-660,

e) residues 748-766,

f) residues 1055-1071, or

g residues 1084-1116,

are included and which are excluded from the scope of claims 16 and 17.

At least for the reasons given in points 1-7 above the rejection of claims 13-15 and the method claims 11 and 21 should be rejected for lack of written description and claims 15-17 for lack of written description and for being indefinite.

4. Conclusion

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1652

Patent Examiner